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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,888	07/23/2003	Franz Enzmann	P66925US1	6760

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,888	ENZMANN, FRANZ	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/27/2007 has been entered.

Response to Amendment

Applicants amendment to the claims filed 08/27/2007 has been entered, claim 6 has been amended. While the word heterogeneous does not appear in applicants specification since Q10 is disclosed as insoluble in water and the combination is in the form of a colloidal dispersion it is inherent that a mixture of just water and Q10 will be a heterogeneous dispersion.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicants arguments with respect to Masterson are persuasive because clearly Masterson's compositions were homogenous solutions, Q10 was solubilized in water by a solubilizing agent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nyce (US 5,660,835, cited by applicants).

Nyce teaches the use of DHEA in treating adenosine depletion, the specification details that ubiquinones including Q_{10} can be administered concurrently with DHEA to counteract Q_{10} depletion in the lungs either separately or simultaneously. See col 5 lin 46-col 7 lin 39. The active compound could be combined with pyrogen free water and formulated into an aerosol, thus meeting the limitation of a spray and aqueous colloidal dispersion. Regarding the limitation that the spray is heterogeneous, from applicant's own specification the last paragraph on page 2 states that ubiquinones are lipophilic substances that are virtually insoluble in water, thus it is inherent that any combination of just water and Q_{10} without the aid of a solubilizer will form a heterogeneous system. Regarding the limitations within claims 7 and 8 that the spray is either an oral or nasal spray, it is inherent that since the aerosolized compositions of Nyce were administered to the lungs the compositions passed through the oral or nasal cavity. Regarding the limitation in claim 8 the amount of ubiquinone Q_{10} is administered in a total amount per day of 1 to 1200 mg/kg body weight per day, thus within this broad range applicants claimed range for the amount of Q10 is inherently met. For instance for a subject with a weight of 60 kg if administered a dose of 10 mg/kg would receive 600 mg of Q10 per day.

Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO 97/42938, cited by applicants).

Keller teaches delivery of a biologically active material (including ubiquinone Q10) is a liposomal formulation for administration in the mouth. See abstract, page 7 lin 19-page 8 lin 15, example 6 and claims 1-2,6. The compositions are administered by an aerosol or pump spray, thus meeting the limitation of a spray and aqueous colloidal dispersion. Regarding the limitation that the spray is heterogeneous, from applicant's own specification the last paragraph on page 2 states that ubiquinones are lipophilic substances that are virtually insoluble in water, thus it is inherent that any combination of just water and Q10 without the aid of a solubilizer will form a heterogeneous system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyce (US 5,660,835, cited by applicants) or alternatively Keller et al. (WO 97/42938, cited by applicants) in view of Nagley et al (US 5,981,601, cited previously by examiner) in view of Beal et al. (Molec. Aspects Med. Vol 18, supplement, pp s169-s179, cited previously by examiner) in view of ISAO (JP 52-130922, cited previously by examiner).

Nyce and Keller are disclosed above, Nyce and Keller do not disclose treatment of the claimed diseases recited within claims 9-13 with Ubiquinone Q_{10}.

Nagely discloses treatment of hereditary optic neuropathy, Parkinson's disease and Alzheimers with therapeutic compositions that included redox compounds such as Ubiquinone Q10. See Abstract lin 1-2, col 3 lin 50-65, col 8 lin 14-16, lin 59-col 9 lin 6. Regarding claim 8 the effective amount of redox compound falls within the range cited by the applicants. See claim 8.

Beal is used to primarily show that the use of coenzyme-Q_{10} as a treatment for Huntington's disease was well known at the time of the invention. See abstract.

Isao is used to primarily show that the use of coenzyme-Q_{10} as a treatment for headaches (meets the limitation of migraine) was well known at the time of the invention. See DERWENT basic abstract.

Thus it follows that applicants claimed invention was *prima fascia* obvious in view of the combination of references above. The claims would have been obvious because it was already well known that the particular techniques of treating hereditary optic neuropathy, Parkinson's disease, Alzheimers, Huntington's disease and headaches through administration of compositions containing ubiquinone Q_{10} was already

recognized in the prior art and it would have been ordinary to one of skill in the art to treat the above diseases through administration of ubiquinone Q_{10} as disclosed within Nyce or Keller.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 9 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 6-8 of copending Application No. 10/424,987. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Specifically both claim a method of treating migraines using an aqueous spray of ubiquinone Q_{10}. As detailed above it is inherent that a combination of water and ubiquinone Q_{10} will form a heterogeneous system because Q_{10} is substantially insoluble in water.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER